Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

In the Matter of	)	
	)	
Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation	)	ET Docket 93-62

REPLY COMMENTS OF THE ELECTROMAGNETIC ENERGY POLICY ALLIANCE

The Electromagnetic Energy Policy Alliance (The Alliance) respectfully submits this Reply to the Comments of the United States Environmental Protection Agency (EPA) and the Food and Drug Administration's Center for Devices and Radiological Health (CDRH/FDA) in the referenced proceeding.

Introduction. The Alliance has studied the Comments in this proceeding and has concluded that with few exceptions most responders recognize that the large and diverse membership of Subcommittee 4 of IEEE Standards Coordinating Committee 28 reflects a more accurate consensus of the scientific community than do smaller panels of selected experts and are supportive of adoption of ANSI/IEEE C95.1-1992 by the Commission. A notable exception is the United States Environmental Protection Agency (EPA) which argues that the Commission should adopt the radiofrequency protection guides in NCRP Report No. 86, Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields, instead of ANSI/IEEE C95.1-1992. The EPA argument is based on a number of statements, several of which the Alliance believes are unconvincing and inappropriate. Also, while the Food and Drug Administration's Center for Devices and Radiological Health (FDA) supports adoption of ANSI/IEEE C95.1-1992, with the exception of the low-power device exclusion, FDA has made statements in its Comments regarding the low-power device exclusion, which the Alliance believes are unconvincing. The statements and issues on which the Alliance will comment are:

1. A relaxation of the maximum permissible exposure (MPE) by a factor of two times at certain microwave frequencies. (EPA)

2. Controlled environment and uncontrolled environment versus occupational exposure and public exposure. (EPA)
3. ELF amplitude modulated RF has not been considered in ANSI/IEEE C95.1-1992 standard. (EPA)
4. The radiofrequency protection guides recommended in NCRP Report No. 86 should be adopted instead of ANSI/IEEE C95.1-1992. (EPA)
5. Certain low power personal communication devices can induce relatively high SARs in portions of the body of nearby persons. (FDA)

1. Relaxation of the maximum permissible exposure (MPE) by a factor of two times at certain microwave frequencies. One reason advanced by the EPA in support of the Commission adopting the radio frequency protection guides found in NCRP Report No. 86 (NCRP, 1986) instead of ANSI/IEEE C95.1-1992 is "[t]heir [NCRP] exposure criteria are more protective at higher frequencies." As further support, the EPA states that "[t]he 1992 ANSI/IEEE allows a two-fold increase in the MPE at high frequencies above that permitted by the current guideline." The Alliance believes that while these statements may appear to buttress their position, the EPA has failed to address at least four factors that must be considered simultaneously when comparing the relative "protection" afforded by the two recommendations: namely,

1. The MPE at the frequency being compared,
2. The averaging (or measurement) time,
3. The peak power permitted relative to the averaging time,
4. The tier under consideration.

For the most protective tier (NCRP's general population, ANSI/IEEE's uncontrolled environment) at 100 GHz, the highest frequency that NCRP has in common with ANSI/IEEE, the MPEs expressed as power density are 1 mW/cm^2 (NCRP) and 10 mW/cm^2 (ANSI/IEEE). The inference is that ipso facto NCRP is more protective. Looking beyond just the MPE, however, the recommendations also include averaging times of 30 min (NCRP) and 37 s (ANSI/IEEE) at 100 GHz. For a single short exposure, e.g., of the order of one second, NCRP permits exposures of 3.6 W/cm^2, a value approaching the threshold for skin burn for small areas, whereas ANSI/IEEE limits the exposure to 0.37 mW/cm^2, approximately one-tenth the NCRP permitted value. Under these conditions, ANSI/IEEE is approximately ten times more "protective" than NCRP.

Recognizing that skin burn thresholds could be exceeded for short exposures at frequencies where surface heating predominates, i.e., above a few 10's of GHz, the

ANSI/IEEE committee (and the NCRP) decreased the averaging time with increasing frequency to avoid this possibility. At 300 GHz, the ANSI/IEEE averaging time and MPE is entirely consistent with well-established criteria for infrared radiation found in the American National Standard for the Safe Use of Lasers, ANSI Z136.1-1993, i.e., 10 s and 10 mW/cm^2.

Further, the absence of peak power density limits in the NCRP criteria allows the pulse amplitude to increase without bound as the pulse width decreases, while the ANSI/IEEE standard contains specific criteria to limit exposure to pulsed RF fields. Specifically, the ANSI/IEEE MPEs limit the peak amplitude of pulses less than 100 ms in duration to one-fifth of the value obtained by time averaging (five such pulses may occur during the averaging time), or 100 kV/m, whichever is smaller. There are no such limitations in the NCRP recommendations.

By way of example, if one compares the ANSI/IEEE MPE with the NCRP criteria for a 100 ms - 100 GHz pulse, the 37 s ANSI/IEEE averaging time limits the peak power density to approximately 740 mW/cm^2 while the 30 min NCRP averaging time allows a peak power density of 18,000 mW/cm^2. In this example, the ANSI/IEEE MPE appears to be approximately ten times more "protective" than NCRP. The difference is even more dramatic for shorter pulses. All factors considered, including the extension of the ANSI/IEEE limits to higher frequencies than NCRP, it is misleading of the EPA to represent NCRP as more "protective" at higher frequencies than ANSI/IEEE.

2. **Controlled environment and uncontrolled environment versus occupational exposure and public exposure.** In their comments in this proceeding, EPA recommends that the Commission use the terms "occupational" and "general population" instead of the ANSI/IEEE designations "controlled environment" and "uncontrolled environment." EPA states that the ANSI/IEEE designations do not apply to population groups, are not well defined and are not discretionary. With respect to the latter, EPA notes that "identification of controlled environments is at the discretion of the operator of a source." As further support for their recommendation of population groups, rather than exposure environments, EPA states that ANSI/IEEE has not allowed for variations in sensitivity of certain subgroups of the population who, consequently, may be more at risk from exposure to RF radiation and points out that the lower NCRP limits "might also include nontechnical employees."

The Alliance believes EPA's reasoning is flawed and that designation of the two tiers as "controlled environment" and "uncontrolled environment," a concept long-used in radiation protection, is far less ambiguous than designation by population type. For example, consider the case where a number of employees are located at the same facility, not all of whom are directly involved with RF producing sources, e.g., office workers, maintenance personnel. Most would argue that only aware individuals directly involved with the RF-producing sources should be subject to the higher MPEs. Based on the ANSI/IEEE definition of "uncontrolled environment," i.e., locations where there is exposure of individuals who have no knowledge or control of their exposures, and which include exposures in the workplace, it is clear that only those individuals who are directly involved with the RF-producing devices would be subject to the higher MPEs for the controlled environment. Under NCRP, everyone employed at the facility would be considered workers, and therefore, subject to the higher occupational limits unless, as pointed out by the EPA, the lower tier "might also include nontechnical employees." The Alliance fails to see how this is better defined and less discretionary than the ANSI/IEEE terminology. The ANSI definitions of the controlled and uncontrolled environment are clear; the identification of these environments is no more discretionary than the identification of areas where exposures may exceed either of the NCRP tiers.

Finally, the practicality of implementation of two tiers based on controlled and uncontrolled environment has been recognized by other standards organizations. For example, the European Committee for Electrotechnical Standardization (CENELEC), in their latest draft (August 12, 1993) of report CLC/SCIIIB, Human Exposure to Electromagnetic Fields: 10 kHz to 300 GHz, uses controlled and uncontrolled environment, defined exactly the same way as in ANSI/IEEE C95.1-1992 to distinguish between its two tiers. Based on the considerable radiation safety experience of its member organizations, the Alliance believes that adoption of the concepts of "controlled" and "uncontrolled" environment by the Commission, instead of "occupational" and general "public," is by far the more practical means of implementing the standard.

3. ELF amplitude modulated RF has not been considered in ANSI/IEEE C95.1-1992 standard. EPA, in its discussion about ELF-modulated RF radiation, states that "[t]he modulation provision for workers in the NCRP guidelines is unique; no other RF exposure guideline contains such a provision." This is followed by the statement "...the effects [responses to nonthermal ELF-modulated RF] information is not yet sufficient to be used as a basis for exposure criteria to protect the public against adverse human

health effects." EPA then notes that NCRP requires a 10-fold reduction (the actual reduction is 5-fold) in the occupational exposure criteria for certain modulation conditions.

The Alliance agrees with EPA that there is insufficient information to relate the results of largely unconfirmed and controversial studies that report modulation-specific efforts, e.g., changes in calcium ion efflux from freshly excised chick brain hemispheres, to human health. In addition to a lack of independent confirmation, these studies report effects associated with "windows" of modulating frequency and field strength. Frequently, specific constraints on the strength and direction of the geomagnetic flux lines are reported before an effect was demonstrated. If found to be important with respect to human health, effects demonstrating intensity "windows" will be a challenge to standards developing bodies. Implicit with such phenomena is the condition that "higher exposures may be safer than lower exposures."

The Alliance believes that ANSI/IEEE is correct when it points out that "[r]esearch on the effects of chronic exposure and speculations on the biological effects of nonthermal interactions have not yet resulted in any meaningful basis for altering the standard." In fact, it is pointed out in the NCRP report that "[i]t is not known whether these effects pose a health risk." Similar statements are found in the 1993 WHO/IRPA Environmental Health Criteria 137 Report Electromagnetic Fields, 300 Hz to 300 GHz, i.e., "[t]he biological significance and possible health impact, if any, of the reported effects cannot be determined at this time." Similarly, the National Radiological Protection Board in the United Kingdom concluded in their 1993 Board Statement on Restrictions on Human Exposure to Static and Time Varying Electromagnetic Fields (Vol. 4, No. 5 of Documents of the NRPB) "[i]nteraction mechanisms for these effects [of ELF amplitude modulated RF fields] are neither well defined nor understood." NRPB continues, "[t]he data do not provide a basis for restrictions on human exposure."

The Alliance agrees with the conclusions of the cited organizations. For reasons given, it should not be surprising that the ELF-modulated provision of NCRP is unique. The Alliance believes that standards should be based on facts and confirmed data. At this time, any effects on human health associated with exposure to weak ELF-amplitude modulated RF fields are a matter of conjecture. Therefore, the Alliance disagrees with EPA that the lack of special provisions for ELF-modulated fields weakens the ANSI/IEEE standard.

4. The radiofrequency protection guides recommended in NCRP Report No. 86 should be adopted instead of ANSI/IEEE C95.1-1992. It is surprising to the Alliance that EPA recommends adoption of the NCRP recommendations instead of ANSI/IEEE C95.1-1992. Except for higher MPEs at the higher microwave frequencies, and an extension of the frequency range, the ANSI/IEEE MPEs and the NCRP RFPGs are similar in the frequency range associated with exposure from most telecommunications systems. Both the ANSI/IEEE MPEs and the NCRP RFPGs are based on limiting the whole-body-averaged SAR to 0.4 W/kg and 0.08 W/kg, the spatial peak SARs to 8 W/kg and 1.6 W/kg, for the controlled environment/occupational exposure and the uncontrolled environment/general public exposure, respectively. That is, both are based on the same factors of safety. Moreover, both criteria are based on the same most sensitive biological endpoint, i.e., disruption of behavior.

It also is surprising that while EPA recommends adoption of the ANSI/IEEE limits for induced and contact current, they only recommend the ANSI/IEEE limits for frequencies between 300 kHz and 100 MHz but not for lower frequencies where shocks and burns are perhaps even more important, i.e., frequencies between 3 kHz and 300 kHz.

Having studied the EPA comments, and having compared the ANSI/IEEE and NCRP field limits, the Alliance has to conclude that EPA apparently is concerned more about specific statements and semantics in the ANSI/IEEE rationale than about the actual numerical values of the exposure limits. With respect to the actual exposure limits, it appears that EPA is in agreement with the growing international consensus reflected in the ANSI/IEEE C95.1-1992 MPEs.

5. Certain low power personal communication devices can induce relatively high SARs in portions of the body of nearby persons. While the Alliance generally concurs with the comments of FDA, the Alliance disagrees with the recommendation that the low-power device exclusion clause not be adopted. The reasons given by FDA are "[r]ecent data from technical publications and other sources indicate that certain lower powered RF devices, such as hand-held, portable, two-way radios, cellular phones, and other personal communication devices can induce relatively high SARs in portions of the body of nearby persons."

The Alliance believes that this statement is not entirely correct. The Alliance agrees that relatively low power radiating devices (radiating power equal to or less than the values stated in 4.2.1.1 and 4.2.2.1 of ANSI/IEEE C95.1-1992) can produce SAR values in

excess of the spatial peak limits of 3 W/kg and 1.6 W/kg, for the controlled and uncontrolled environments, respectively, if placed arbitrarily close to the human body. However, the Alliance is not aware of any generally accepted evidence in the extant literature to indicate that the corresponding peak SAR limits are exceeded by low power devices that meet the provisions of 4.2.1.1 and 4.2.2.1 when all of the elements of the radiating structure are at least 2.5 cm from any part of the body excluding the hands, as the low power device exclusion requires. The minimum separation distance, which the Alliance believes was specified to distinguish between hand-held and body mounted radio transceivers, e.g., it is stated in 6.10 of the ANSI/IEEE Rationale that "...it is unlikely for devices such as low-power hand held radios (where the radiating structure is not maintained 2.5 cm or less from the body) to expose the user in excess of the exclusion clause...," is an essential part of the low power device exclusion. If the distance requirement is overlooked, the efficacy of the low power device exclusion can be totally misconstrued.

The Alliance is unaware of evidence in the extant literature to indicate that devices meeting the low power device exclusion, when used as intended, could produce "relatively high SARs in portions of the body of nearby persons." While one could always envision some situation where a hand-held device deliberately misused could, perhaps, produce SARs in excess of the limit for the controlled environment, averaging time constraints make even this hypothetical situation improbable.

Finally, the low power device exclusion is based on experimental measurements collected over a period of about twenty years using methodologies that overstate rather than understate the SAR values.

The Alliance believes that the FDA has not offered convincing evidence in support of their position that the Commission should not adopt the low power device exclusion.

Conclusion. The Alliance has studied the Comments in this proceeding and has not seen any convincing evidence to indicate that adoption by the Commission of ANSI/IEEE C95.1-1992 is not appropriate. Disagreement about statements and explanations in the ANSI/IEEE Rationale relating to a perceived failure to consider nonthermal effects, modulation-specific sequelea, etc., are not compelling reasons for adoption of the NCRP recommendations instead of the far more comprehensive and detailed ANSI/IEEE standard. EPA arguments notwithstanding, the Alliance believes that implementation of the ANSI/IEEE standard is far less ambiguous than would be

earlier standards and recommendations. Therefore, the Alliance recommends that the Commission should adopt the ANSI/IEEE standard.

Reflectfully submitted,

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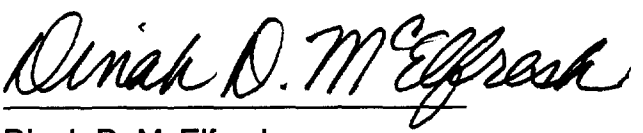

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